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Attorney Docket No. 9368.5

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

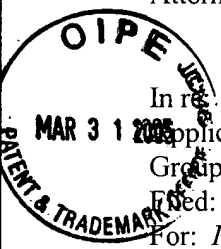
In re: Smith et al.

Application Serial No.: 10/804,331

Group Art Unit: 1648

Filed: March 19, 2004

For: *Improved Alphavirus Replicons and Helper Constructs*



Date: March 31, 2005

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. § 1.97(b)**

Sir:

Attached is a list of documents on Form PTO-1449, together with a copy of any listed foreign patent document and/or non-patent literature. A copy of any listed U.S. patent and/or U.S. patent application publication is not provided herewith in accordance with the waiver by the U.S. Patent and Trademark Office of requirements under 37 C.F.R. § 1.98(a)(2)(i) for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC § 371 after June 30, 2003.

It is requested that these documents be considered by the Examiner and officially made of record in accordance with the provisions of 37 C.F.R. § 1.56 and Section 609 of the MPEP.

No fee is believed due. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,

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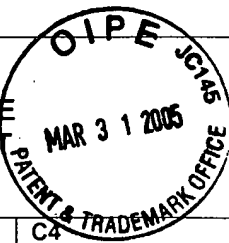
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Sheena L. Donnelly

Substitute form 1449A/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				Application Number	10/804,331
(use as many sheets as necessary)		Filing Date	March 19, 2004		
Sheet <b>C1</b> of <b>C4</b>		First Named Inventor	Smith		
		Group Art Unit	1648		
		Examiner Name	Unknown		
		Attorney Docket Number	9368.5		

U.S. PATENTS AND PATENT PUBLICATIONS					
Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code (if known)		
	1.	US-2001/0016199		Johnston et al.	08/23/2001
	2.	US-2002/0018766		Roberts et al.	02/14/2002
	3.	US-2002/0034521		Lee et al.	03/21/2002
	4.	US-2002/0102273		Grieve et al.	08/01/2002
	5.	US-2002/0141975		Olmsted et al.	08/31/2004
	6.	US-2002/0164582		Hart et al.	11/07/2002
	7.	US-2003/0021766		Vadjy et al.	01/30/2003
	8.	US-2003/0091591		Xiong et al.	05/15/2003
	9.	US-2003/0096397		Schlesinger et al.	05/22/2003
	10.	US-2003/0120060		Goncziol et al.	06/26/2003
	11.	US-2003/0152590		Hevey et al.	08/14/2003
	12.	US-2003/0232036		Johnston et al.	12/18/2003
	13.	US-2004/0008458		Kase et al.	01/15/2004
	14.	US-2004/0009183		Lee et al.	01/15/2004
	15.	US-2004/0009945		Lee et al.	01/15/2004
	16.	US-2004/0030117		Johnston et al.	02/12/2004
	17.	US-2004/0121466		Johnston et al.	06/24/2004
	18.	US-2004/0146859		Hart et al.	07/29/2004
	19.	US-2004/0166573		Smith et al.	08/26/2004
	20.	US-2004/0208848		Smith et al.	10/21/2004
	21.	US-2005/0031592		Doolan et al.	02/10/2005
	22.	US-2005/0054107		Chulay et al.	03/10/2005
	23.	US-4,708,871		Geysen	11/24/1987
	24.	US-5,521,082		Lewis et al.	05/28/1996
	25.	US-5,703,057		Johnston et al.	12/30/1997
	26.	US-5,726,022		Burner	03/10/1998
	27.	US-5,831,016		Wang et al.	3/11/1998
	28.	US-5,843,723		Dubensky et al.	12/01/1998
	29.	US-5,853,719		Nair et al.	12/29/1998
	30.	US-5,958,738		Lindermann et al.	09/28/1999
	31.	US-5,989,553		Johnston et al.	11/23/1999
	32.	US-6,194,191		Zhang et al.	02/27/2001
	33.	US-6,197,502		Renner et al.	03/06/2001
	34.	US-6,267,967		Johnston et al.	07/31/2001
	35.	US-6,306,388		Nair et al.	10/23/2001
	36.	US-6,485,958		Blanch et al.	11/26/2002
	37.	US-6,495,143		Lee et al.	12/01/2001
	38.	US-6,521,235		Johnston et al.	02/18/2003
	39.	US-6,531,135		Johnston et al.	03/11/2003
	40.	US-6,541,010		Johnston et al.	04/01/2003
	41.	US-6,583,121		Johnston et al.	06/24/2003
	42.	US-6,767,699		Polo et al.	07/27/2004
	43.	US-6,770,283		Garoff et al.	08/03/2003
	44.	US-6,783,939		Olmsted et al.	08/31/2004
	45.	US-6,844,188		MacDonald et al.	01/18/2005

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute form 1449/PTO			<b>Complete if Known</b>		
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>			Application Number	10/804,331	
			Filing Date	March 19, 2004	
			First Named Inventor	Smith	
			Group Art Unit	1648	
			Examiner Name	Unknown	
Sheet	C2	of	C4	Attorney Docket Number	9368.5

(use as many sheets as necessary)

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
	46.		WO 99/07834			02/18/1999
	47.		WO 99/08706			02/25/1999
	48.		WO 01/16343 A1			03/08/2001
	49.		WO 00/39302			07/06/2000
	50.		WO 02/03917			01/17/2002
	51.		WO 02/04493			01/17/2002
	52.		WO 03/083065 A2			10/09/2003
	53.		WO 04/055166			07/01/2004
	54.		WO 04/055167			07/01/2004
	55.		WO 04/085660			10/07/2004
	56.		WO 05/007689			01/27/2005

OTHER NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T
	57.	Balasuriya et al. "Alphavirus Replicon Particles Expressing the Two Major Envelope Proteins of Equine Arteritis Virus Induce High Level Protection Against Challenge with Virulent Virus in Vaccinated Horses" Vaccine 20:1609-1617 (2002)	
	58.	Barry et al. "Expression Library Immunization to Discover and Improve Vaccine Antigens" Immunological Reviews 199:68-83 (2004)	
	59.	Bell et al. "Effect of Low NaCl Medium on the Envelope Glycoproteins of Sindbis Virus" Journal of Virology 25(3):764-769 (1978)	
	60.	Bergman et al. "Long-Term Survival of Dogs with Advanced Malignant Melanoma after DNA Vaccination with Xenogeneic Human Tyrosinase: A Phase I Trial" Clin. Cancer Research 9:1284-1290 (2003)	
	61.	Bernard et al. "Mutations in the E2 Glycoprotein of Venezuelan Equine Encephalitis Virus Confer Heparan Sulfate Interaction, Low Morbidity, and Rapid Clearance from Blood of Mice" Virology 276:93-103 (2000)	
	62.	Bourne et al. "Preconception Immunization with a Cytomegalovirus (CMV) Glycoprotein Vaccine Improves Pregnancy Outcome in a Guinea Pig Model of Congenital CMV Infection" The Journal of Infectious Diseases 183:59-64 (2001)	
	63.	Carlson et al. "Expression, Purification and Characterization of a Soluble Form of Human Cytomegalovirus Glycoprotein B" Virology 239:198-205 (1997)	
	64.	Casimiro et al. "Vaccine-Induced Immune Responses in Rodents and Nonhuman Primates by Use of a Humanized Immunodeficiency Virus Type 1 pol Gene" Journal of Virology 76:185-195 (2002)	
	65.	Chatterjee et al. "Modification of Maternal and Congenital Cytomegalovirus Infection by Anti-Glycoprotein B Antibody Transfer in Guinea Pigs" The Journal of Infectious Diseases 183:1547-1553 (2001)	
	66.	Davis et al. "A Single Nucleotide Change in the E2 Glycoprotein Gene of Sindbis Virus Affects Penetration Rate in Cell Culture and Virulence in Neonatal Mice" Proc. Natl. Acad. Sci. USA 83:6771-6775 (1986)	
	67.	Davis et al. 1989. In Vitro Synthesis of Infectious Venezuelan Equine Encephalitis Virus RNA from a cDNA Clone: Analysis of A Viable Deletion Mutant. Virology 171:189-204	
	68.	Geisbert et al. "Evaluation in Nonhuman Primates of Vaccines Against Ebola Virus" Emerging Infect. Dis. 8(5):503-507 (2002)	
	69.	Geysen et al. "A Priori Delineation of a Peptide which Mimics a Discontinuous Antigenic Determinant" Molecular Immunology 23(7):709-715 (1986)	

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70.	Geysen et al. "Use of Peptide Synthesis to Probe Viral Antigens for Epitopes to a Resolution of a Single Amino Acid" Proceedings of the National Academy of Sciences of the United States of America 81(13):3998-4002(1984)
71.	Golzio et al. "Cell Synchronization Effect on Mammalian Cell Permeabilization and Gene Delivery by Electronic Field" Biochim. Biophys. Acta 1563:23-28 (2002)
72.	Goncziol and Plotkin "Development of a Cytomegalovirus Vaccine: Lessons from Recent Clinical Trials" Exp. Opin. Biol. Ther. 1(3):401-412 (2001)
73.	Gyulai et al. "Cytotoxic T Lymphocyte (CTL) Responses to Human Cytomegalovirus pp65, IE1-Exon4, gB, pp150, and pp28 in Healthy Individuals: Reevaluation of Prevalence of IE1-Specific CTLs" J. Infect. Dis. 181:1537-1546(2000)
74.	Hahn et al. "Infectious Sindbis Virus Transient Expression Vectors for Studying Antigen Processing and Presentation" Proc. Natl. Acad. Sci. USA 89:2679-2683 (1992)
75.	Hariharan et al. "DNA Immunization Against Herpes Simplex Virus: Enhanced Efficacy Using a Sindbis Virus-Based Vector" Journal of Virology 72(2):950-958 (1998)
76.	Heiser et al. "Autologous Dendritic Cells Transfected with Prostate-Specific Antigen RNA Stimulate CTL Responses Against Metastatic Prostate Tumors" J. Clinical Inv. 109(3):409-417 (2002)
77.	Hevey et al. "Marburg Virus Vaccines Based upon Alphavirus Replicons Protect Guinea Pigs and Nonhuman Primates" Virology 251:28-37 (1998)
78.	Hill et al. "RNA-RNA Recombination in Sindbis Virus: Roles of the 3' Conserved Motif, Poly (A) Tail, and Nonviral Sequences of Template RNAs in Polymerase Recognition and Template Switching" Journal of Virology 71:2693-2704 (1997)
79.	International Search Report issued for PCT/2004/021772; mailed on December 28, 2004
80.	International Search Report issued for PCT/US03/39723; mailed on August 17, 2004
81.	International Search Report issued for PCT/US03/39725; mailed on December 3, 2004
82.	Koller et al. "A High-Throughput Alphavirus-Based Expression Cloning System for Mammalian Cells" Nature Biotech. 19:851-855 (2001)
83.	Kumamoto et al. "Induction of Tumor-Specific Protective Immunity by in situ Langerhans Cell Vaccine" Nature Biotech. 20:64-69 (2002)
84.	Leitner et al. "Enhancement of Tumor-Specific Immune Response with Plasmid DNA Replicon Vectors" Cancer Research 60:51-55 (2000)
85.	Liljestrom et al. "In Vitro Mutagenesis of a Full-Length cDNA Clone of Semliki Forest Virus: the Small 6,000-Molecular-Weight Membrane Protein Modulates Virus Release" Journal of Virology 65:4107-4113 (1991)
86.	Lu et al. "Transmission of Replication-Defective Sindbis Helper Vectors Encoding Capsid and Envelope Proteins" Journal of Virological Methods 91(1):59-65 (2001)
87.	Lundstrom "Alphavirus Vectors: Applications for DNA Vaccine Production and Gene Expression" Intervirology 43:247-257 (2000)
88.	Maecker et al. "Use of Overlapping Peptide Mixtures as Antigens for Cytokine Flow Cytometry" Journal of Immunological Methods 255:27-40 (2001)
89.	McCue and Anders "Soluble Expression and Complex Formation of Proteins Required for HCMV DNA Replication Using the SFV Expression System" Protein Expression and Purification 13:301-312 (1998)
90.	Morello et al. "Suppression of Murine Cytomegalovirus (MCMV) Replication with a DNA Vaccine Encoding MCMV M84 (a Homolog of Human Cytomegalovirus pp65)" Journal of Virology 74(8):3696-3708 (2000)
91.	Olmsted et al. "Alphavirus Vectors and Virosomes with Modified HIV Genes for Use in Vaccines" U.S. Patent Application Serial No. 10/929,234, filed in the U.S. Patent and Trademark Office on August 30, 2004
92.	Olmsted et al. "Characterization of Sindbis Virus Epitopes Important for Penetration in Cell Culture and Pathogenesis in Animals" Virology 148:245-254 (1986)
93.	Overwijk et al. "Creating Therapeutic Cancer Vaccines: Notes from the Battlefield" Trends in Immunol. 22(1):5-7 (2001)
94.	Pardoll "Cancer Vaccines" Nature Medicine Vaccine Supplement 4(5):525-531 (1998)
95.	Pardoll "Spinning Molecular Immunology into Successful Immunotherapy" Nature Reviews - Immunology 2:227-238 (2002)

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		First Named Inventor	Smith		
		Group Art Unit	1648		
		Examiner Name	Unknown		
Sheet	C4	of	C4	Attorney Docket Number	9368.5

96.	Pedersen et al. "Separation, Isolation, and Immunological Studies of the Structural Proteins of Venezuelan Equine Encephalomyelitis Virus" J. Virology 14(4):740-744 (1974)	
97.	Plotkin et al. "Multicenter Trial of Towne Strain Attenuated Virus Vaccine in Seronegative Renal Transplant Recipients" Transplantation 58(11):1176-1178 (1994)	
98.	Polo et al. "Stable Alphavirus Packaging Cell Lines for Sindbis Virus and Semliki Forest Virus-Derived Vectors" Proc. Natl. Acad. Sci. 96:4598-4603 (1999)	
99.	Ragupathi et al. "The Case for Polyvalent Cancer Vaccines that Induce Antibodies" Expert Rev. Vaccines 1(2):193-206 (2002)	
100.	Sadanaga et al. "Dendritic Cell Vaccination with MAGE Peptide is a Novel Therapeutic Approach for Gastrointestinal Carcinomas" Clin Cancer Research 7:2277-2284 (2001)	
101.	Schlesinger and Dubensky Jr. "Alphavirus Vectors for Gene Expression and Vaccines" Current Opinion in Biotechnology 10(5):434-439 (1999)	
102.	Slepushkin et al. "Large Scale Purification of a Lentiviral Vector by Size Exclusion Chromatography or Mustang Q Ion Exchange Capsule" Bioprocessing Journal pp 89-94 (Sept.-Oct. 2003)	
103.	Technical Bulletin NO. 166: RiboMAX Large Scale RNA Production Systems – SP6 and T7; Promega Corporation p. 1-11; Revised 09/01; <a href="http://www.promega.com/tbs/tb166.pdf">http://www.promega.com/tbs/tb166.pdf</a> on 11/04/2004	
104.	Temperton "DNA Vaccines Against Cytomegalovirus: Current Progress" International Journal of Antimicrobial Agents 19:169-172 (2002)	
105.	Waite et al. "Inhibition of Sindbis Virus Production by Media of Low Ionic Strength: Intracellular Events and Requirements for Reversal" Journal of Virology 5:60-71 (1970)	
106.	Walter et al. "Reconstitution of Cellular Immunity Against Cytomegalovirus in Recipients of Allogeneic Bone Marrow by Transfer of T-Cell Clones from the Donor" The New England Journal of Medicine 333(16):1038-1044 (1995)	
107.	Ward et al. "Immunotherapeutic Potential of Whole Tumor Cells" Cancer Immunol. Immunother. 51:351-357 (2002)	
108.	Williamson et al. "Designing HIV-1 Subtype C Vaccines for South Africa" South African Journal of Science 96:318-324 (2000)	
109.	Wilson et al. "Vaccine Potential of Ebola Virus VP24, VP30, VP35 and VP40 Proteins" Virology 286:384-390 (2001)	
110.	Yamanaka et al. "Enhancement of Antitumor Immune Response in Glioma Models in Mice by Genetically Modified Dendritic Cells Pulsed with Semliki Forest Virus-Mediated Complementary DNA" J. Neurosurgery 94:474-481 (2001)	
111.	Yamanaka et al. "Marked Enhancement of Antitumor Immune Responses in Mouse Brain Tumor Models by Genetically Modified Dendritic Cells Producing Semliki Forest Virus-Mediated Interleukin-12" J. Neurosurgery 97:611-618 (2002)	
112.	Ying et al. "Cancer Therapy Using a Self-Replicating RNA Vaccine" Nature Medicine 5(7):823-827 (1999)	

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